Complete Summary

GUIDELINE TITLE

Medical management of tubal pregnancy.

BIBLIOGRAPHIC SOURCE(S)

American College of Obstetricians and Gynecologists (ACOG). Medical management of tubal pregnancy. Washington (DC): American College of Obstetricians and Gynecologists (ACOG); 1998 Dec. 7 p. (ACOG practice bulletin; no. 3). [31 references]

GUIDELINE STATUS

This is the current release of the guideline.

According to the guideline developer, this guideline is still considered to be current as of December 2004, based on a review of literature published that is performed every 18-24 months following the original guideline publication.

COMPLETE SUMMARY CONTENT

SCOPE

DISEASE/CONDITION(S)

Tubal ectopic pregnancy

GUIDELINE CATEGORY

Counseling
Diagnosis

Management
Treatment

CLINICAL SPECIALTY

Obstetrics and Gynecology

INTENDED USERS

Physicians

GUIDELINE OBJECTIVE(S)

- To aid practitioners in making decisions about appropriate obstetric and gynecologic care
- To present evidence, including risks and benefits, about methotrexate as an alternative treatment for selected ectopic pregnancies

TARGET POPULATION

Pregnant women presenting with signs and symptoms of ectopic pregnancy

INTERVENTIONS AND PRACTICES CONSIDERED

Diagnosis

1. Serial beta subunit of human chorionic gonadotropin (beta-hCG) test
2. Transvaginal ultrasonography
3. Serum progesterone levels

Management/Treatment

1. Blood test for renal, liver, and bone marrow function; beta-hCG level; blood type; Rh factor; and the presence of antibodies
2. Rh immune globulin for Rh negative patients
3. Methotrexate
4. Monitoring patients for signs and symptoms of tubal rupture and treatment failure
5. Patient counseling and education
6. Repeat beta-hCG level
7. Second dose of methotrexate or surgery if needed

MAJOR OUTCOMES CONSIDERED

- Risk factors associated with ectopic pregnancy
- Sensitivity and specificity of diagnostic tests
- Incidence of heterotopic pregnancy
- Success rate of methotrexate regimen
- Cost-effectiveness of methotrexate treatment

METHODOLOGY

METHODS USED TO COLLECT/SELECT EVIDENCE

Hand-searches of Published Literature (Primary Sources)
Hand-searches of Published Literature (Secondary Sources)
Searches of Electronic Databases

DESCRIPTION OF METHODS USED TO COLLECT/SELECT THE EVIDENCE

The MEDLINE database, the Cochrane Library, and American College of Obstetricians and Gynecologists' (ACOG's) own internal resources and documents were used to conduct a literature search to locate relevant articles published between January 1985 and June 1998. The search was restricted to articles published in the English language. Priority was given to the articles reporting results of original research although review articles and commentaries also were consulted. Abstracts of research presented at symposiums and scientific conferences were not considered adequate for inclusion in this document.

Guidelines published by organizations or institutions such as the National Institutes of Health and ACOG were reviewed, and additional studies were located by reviewing bibliographies of identified articles.

NUMBER OF SOURCE DOCUMENTS

Not stated

METHODS USED TO ASSESS THE QUALITY AND STRENGTH OF THE EVIDENCE

Weighting According to a Rating Scheme (Scheme Given)

RATING SCHEME FOR THE STRENGTH OF THE EVIDENCE

Studies were reviewed and evaluated for quality according to the method outlined by the U.S. Preventive Services Task Force.

I Evidence obtained from at least one properly designed randomized controlled trial

II-1 Evidence obtained from well-designed controlled trials without randomization

II-2 Evidence obtained from well-designed cohort or case-control analytic studies, preferably from more than one center or research group

II-3 Evidence obtained from multiple time series with or without the intervention. Dramatic results in uncontrolled experiments also could be regarded as this type of evidence.

III Opinions of respected authorities, based on clinical experience, descriptive studies, or reports of expert committees

METHODS USED TO ANALYZE THE EVIDENCE

Systematic Review

DESCRIPTION OF THE METHODS USED TO ANALYZE THE EVIDENCE

Not stated

METHODS USED TO FORMULATE THE RECOMMENDATIONS

Expert Consensus

DESCRIPTION OF METHODS USED TO FORMULATE THE RECOMMENDATIONS

Analysis of available evidence was given priority in formulating recommendations. When reliable research was not available, expert opinions from obstetrician-gynecologists were used. See also the "Rating Scheme for the Strength of Recommendations" field regarding Grade C recommendations.

RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS

Based on the highest level of evidence found in the data, recommendations are provided and graded according to the following categories:

A. The recommendation is based on good and consistent scientific evidence.
B. The recommendation is based on limited or inconsistent scientific evidence.
C. The recommendation is based primarily on consensus and expert opinion.

COST ANALYSIS

There is evidence that methotrexate therapy is a cost-effective treatment for small unruptured ectopic pregnancies when compared with laparoscopic salpingostomy. The direct cost advantages are due to elimination of operating room use, anesthesia services, and surgical fees. Indirect costs decrease as a result of quicker recovery times; however, the amount of savings depends on the proportion of patients eligible to receive medical therapy and the overall success rate. A study comparing direct costs of methotrexate with laparoscopic salpingostomy found there are significant savings if methotrexate is used as the primary therapy. An additional study looked retrospectively at patients treated for ectopic pregnancy and also found methotrexate was cost-effective.

METHOD OF GUIDELINE VALIDATION

Internal Peer Review

DESCRIPTION OF METHOD OF GUIDELINE VALIDATION

Practice Bulletins are validated by two internal clinical review panels composed of practicing obstetrician-gynecologists generalists and sub-specialists. The final guidelines are also reviewed and approved by the American College of Obstetricians and Gynecologists (ACOG) Executive Board.

RECOMMENDATIONS

MAJOR RECOMMENDATIONS

The grades of evidence (I-III) and levels of recommendations (A-C) are defined at the end of "Major Recommendations" field.

The following recommendations are based on limited or inconsistent evidence (Level B):

- Intramuscular methotrexate is an appropriate method for treating selected patients with small, unruptured tubal pregnancies.*
- Successful treatment with methotrexate may require more than one dose of methotrexate.*
- Failure of beta subunit of human chorionic gonadotropin (beta-hCG) levels to decrease by at least 15% from day 4 to day 7 after methotrexate administration indicates the need for an additional dose of methotrexate or surgery.*

*Evidence is limited but consistent.

The following recommendation is based primarily on consensus and expert opinion (Level C):

- There may be a role for expectant management of hemodynamically stable patients with presumptive ectopic pregnancy in whom beta-hCG levels are low(<200 mIU/mL) and declining.

Definitions:

Grades of Evidence

I Evidence obtained from at least one properly designed randomized controlled trial

II-1 Evidence obtained from well-designed controlled trials without randomization

II-2 Evidence obtained from well-designed cohort or case-control analytic studies, preferably from more than one center or research group

II-3 Evidence obtained from multiple time series with or without the intervention. Dramatic results in uncontrolled experiments could also be regarded as this type of evidence.

III Opinions of respected authorities, based on clinical experience, descriptive studies, or reports of expert committees

Levels of Recommendations

A. The recommendation is based on good and consistent scientific evidence.
B. The recommendation is based on limited or inconsistent scientific evidence.
C. The recommendation is based primarily on consensus and expert opinion.

CLINICAL ALGORITHM(S)

None provided

EVIDENCE SUPPORTING THE RECOMMENDATIONS

TYPE OF EVIDENCE SUPPORTING THE RECOMMENDATIONS

The type of supporting evidence is identified and graded for each recommendation (see "Major Recommendations").

BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

POTENTIAL BENEFITS

- Improved treatment of tubal ectopic pregnancies with methotrexate
- Methotrexate therapy is a cost-effective treatment for small unruptured ectopic pregnancies when compared with laparoscopic salpingostomy.

POTENTIAL HARMS

Adverse Effects Associated with Methotrexate Treatment

- Drug side effects: nausea, vomiting, stomatitis, diarrhea, gastric distress, dizziness, severe neutropenia (rare), reversible alopecia (rare), pneumonitis
- Treatment effects: increase in abdominal pain (occurs in up to two thirds of patients), increase in beta subunit of human chorionic gonadotropin (beta-hCG) levels during first 1 to 3 days of treatment, vaginal bleeding or spotting
- Signs of treatment failure and tubal rupture: significantly worsening abdominal pain, regardless of change in beta-hCG levels; hemodynamic instability; levels of beta-hCG that do not decline by at least 15% between day 4 and day 7 postinjection; increasing or plateauing beta-hCG levels after the first week of treatment

CONTRAINDICATIONS

CONTRAINDICATIONS

Absolute Contraindications

- Breastfeeding
- Overt or laboratory evidence of immunodeficiency
- Alcoholism, alcoholic liver disease, or other chronic liver disease
- Preexisting blood dyscrasias, such as bone marrow hypoplasia, leukopenia, thrombocytopenia, or significant anemia
- Known sensitivity to methotrexate
- Active pulmonary disease
- Peptic ulcer disease
- Hepatic, renal, or hematologic dysfunction

Relative Contraindications

- Gestational sac $\geq$3.5 cm
- Embryonic cardiac motion

QUALIFYING STATEMENTS

QUALIFYING STATEMENTS

These guidelines should not be construed as dictating an exclusive course of treatment or procedure. Variations in practice may be warranted based on the needs of the individual patient, resources, and limitations unique to the institution or type of practice.

IMPLEMENTATION OF THE GUIDELINE

DESCRIPTION OF IMPLEMENTATION STRATEGY

An implementation strategy was not provided.

INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

IOM CARE NEED

Getting Better

IOM DOMAIN

Effectiveness
Patient-centeredness

IDENTIFYING INFORMATION AND AVAILABILITY

BIBLIOGRAPHIC SOURCE(S)

American College of Obstetricians and Gynecologists (ACOG). Medical management of tubal pregnancy. Washington (DC): American College of

Obstetricians and Gynecologists (ACOG); 1998 Dec. 7 p. (ACOG practice bulletin; no. 3). [31 references]

ADAPTATION

Not applicable: The guideline was not adapted from another source.

DATE RELEASED

1998 Dec (reviewed 2004)

GUIDELINE DEVELOPER(S)

American College of Obstetricians and Gynecologists - Medical Specialty Society

SOURCE(S) OF FUNDING

American College of Obstetricians and Gynecologists (ACOG)

GUIDELINE COMMITTEE

American College of Obstetricians and Gynecologists (ACOG) Committee on Practice Bulletins-Obstetrics

COMPOSITION OF GROUP THAT AUTHORED THE GUIDELINE

Not stated

FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST

Not stated

GUIDELINE STATUS

This is the current release of the guideline.

According to the guideline developer, this guideline is still considered to be current as of December 2004, based on a review of literature published that is performed every 18-24 months following the original guideline publication.

GUIDELINE AVAILABILITY

Electronic copies: Not available at this time.

Print copies: Available for purchase from the American College of Obstetricians and Gynecologists (ACOG) Distribution Center, PO Box 4500, Kearneysville, WV 25430-4500; telephone, 800-762-2264, ext. 192; e-mail: sales@acog.org. The ACOG Bookstore is available online at the ACOG Web site.

AVAILABILITY OF COMPANION DOCUMENTS

None available

PATIENT RESOURCES

None available

NGC STATUS

This NGC summary was completed by ECRI on January 14, 2005.

COPYRIGHT STATEMENT

DISCLAIMER

NGC DISCLAIMER

The National Guideline Clearinghouse™ (NGC) does not develop, produce, approve, or endorse the guidelines represented on this site.

All guidelines summarized by NGC and hosted on our site are produced under the auspices of medical specialty societies, relevant professional associations, public or private organizations, other government agencies, health care organizations or plans, and similar entities.

Guidelines represented on the NGC Web site are submitted by guideline developers, and are screened solely to determine that they meet the NGC Inclusion Criteria which may be found at http://www.guideline.gov/about/inclusion.aspx.

NGC, AHRQ, and its contractor ECRI make no warranties concerning the content or clinical efficacy or effectiveness of the clinical practice guidelines and related materials represented on this site. Moreover, the views and opinions of developers or authors of guidelines represented on this site do not necessarily state or reflect those of NGC, AHRQ, or its contractor ECRI, and inclusion or hosting of guidelines in NGC may not be used for advertising or commercial endorsement purposes.

Readers with questions regarding guideline content are directed to contact the guideline developer.

Date Modified: 5/1/2006